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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,449	02/28/2002	Michael L. Blomquist	9015.141US01	9068

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EXAMINER
CABRERA, ZOILA E

ART UNIT	PAPER NUMBER
2125	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/087,449	BLOMQUIST, MICHAEL L.
	Examiner	Art Unit	
	Zoila E. Cabrera	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>21 April 2005</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-25</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-25</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

U.S. Patent and Trademark Office

PTOL-326 (Rev. 1-04)   Office Action Summary   Part of Paper No./Mail Date 20050610

DETAILED ACTION

Claim Rejections - 35 USC § 102

1.   Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by **Estes et al. (US 2003/0114836)**.

Claims 1-25 are so broad as to read in **Estes**, who discloses a medication delivery system and monitor comprising:

With respect to claims 1-7, **Estes** discloses,

- a method of programming an ambulatory infusion pump from a computer, the ambulatory infusion pump programmed to execute a delivery program, the delivery program being driven by operating parameters (Fig. 1-2), the method comprising: generating a table on the computer, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program (Fig. 3A, element 300; Fig. 5, Alarm/Event Marker Table, i.e., the Table has rows that includes a plurality of cells such as the cell where the time is indicated, "12:58 AM" and the cell "Bolus Est."); entering an operating parameter into at least one of the cells (Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from **the event marker table that have been logged by the user**"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format **depending on user's settings**", [0064], lines 13-15, i.e., "At least **some of these events can be taken as inputs to the**

bolus estimator 128 in calculating an insulin dosage"; [0040] lines 1-3 and 8-

10); and downloading the operating parameters into the pump (Page 6, [0060],

lines 6-8, i.e., "The event markers can be logged into the pump and stored for

later downloading or entered directly into the running software program"; 0035,

lines 1-7);

- the table includes a plurality of rows, each row relating to a different set of

  operating parameters, each set of operating parameters defining a different

  delivery schedule for the pump (Fig. 5, Alarm/Event Marker Table);

- at least one cell within each row is configured for a unique identifying name,

  wherein the unique identifying name identifies the operating parameters in the

  same row of as the unique identifying name (Fig. 5, i.e., Susp. On at 12:57 AM);

- the pump has memory and runs a delivery program and downloading the

  operating parameters includes downloading the operating parameters into the

  pump includes downloading the operating parameters into the memory (0035,

  lines 1-7; Fig. 1, element 106; Fig. 2, element 132, 100);

- the pump is programmed to run a delivery program, the method further

  comprising running the delivery program, thereby executing the operating

  parameters (Fig. 6);

- the pump has memory and is programmed to run a delivery program, the method

  further comprising: downloading all rows of operating parameters to the infusion

  pump; and storing the operating parameters in the memory (0035, lines 1-7; Fig.

  1-2, elements 106, 132; Fig. 3A, element 300);

- 7. The method of claim 6 further comprising: selecting one unique identifying name (Fig. 6, i.e., BOLUS, SUSPEND, or BASAL); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (Fig. 6, i.e., SUSPEND).

As for claim 8, **Estes** discloses

- a method of operating a pump, the pump having a memory and a pump mechanism, the method comprising: receiving from a computer, a plurality of data sets, each data set containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from **the event marker table that have been logged by the user**"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format **depending on user's settings**"; [0064], lines 13-15, i.e., "At least **some of these events can be taken as inputs to the bolus estimator 128** in calculating an insulin dosage"); storing the plurality of data sets in memory (Fig. 1, element 106); selecting one of the plurality of data sets (fig. 6, SUSPEND, BOLUS, BASAL); and running a delivery program wherein the delivery program executes the operating parameters in the selected one of the plurality of data sets, the operating parameters defining a delivery schedule for controlling the pump mechanism (Fig. 6, BOLUS DELIVERY).

With respect to claims 9-11, **Estes** discloses,

- an apparatus for programming an infusion pump, the pump programmed to

  execute a delivery program, the delivery program programmed to process

  operating parameters, the operating parameters defining operating of the pump

  (Fig. 6), the apparatus comprising: a data port; a data entry device (Fig. 2,

  elements 132, 130); and a processor in data communication with the data port

  and the data entry device (Fig. 1, element 102), the processor programmed to (a)

  generate a table, the table containing a row, the row having a plurality of cells,

  each cell in the row relating to a different operating parameter for the delivery

  program (Fig. 3A, element 300; Fig. 5, Alarm/Event Marker Table); (b) receive

  data from the data entry device (Page 6, [0060], lines 1-6, i.e., "The graph is

  derived from carbohydrate consumption events from **the event marker table**

  that have been logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time

  change is displayed in either 12 or 24 hr format **depending on user's settings**";

  [0064], lines 13-15, i.e., "At least **some of these events can be taken as inputs**

  to the bolus estimator 128 in calculating an insulin dosage") and display the

  data in one or more of the cells (Fig. 1, elements 108, 114; Fig. 5, Alarm/Event

  Marker Table; Page 6, [0059]-[0061]); and (c) download the operating

  parameters displayed in the cells to the infusion pump (Fig. 5, i.e., Susp. On 2:00

  pm; Page 6, [0060], lines 6-8, i.e., "The event markers can be logged into the

  pump and stored for later downloading or entered directly into the running

  software program");

- the processor is further programmed to generate a plurality of rows in the table, each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.(Fig. 5, Alarm/Event Marker Table);

- each row in the table includes at least one cell configured to receive a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (Fig. 5, i.e., Susp. On at 12:57 AM).

As for claims 12-18, **Estes** discloses,

- a method of operating an infusion pump for delivering a therapeutic agent into the body of a user, the infusion pump being programmable and including memory, the infusion pump being programmed to run a delivery program, the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (Figs. 1-2, 5 and 6), the method comprising: storing a data set in the memory, the data set including a set of operating parameters defining a delivery schedule, at least one of the operating parameters being a uniquely identifying name (Fig. 1, element 106, Fig. 6, BOLUS, SUSPEND, BASAL; Page 6, [0058]); selecting the uniquely identifying name thereby assigning the set of operating parameters identified by the uniquely identifying name to the delivery program (0072, lines 1-9 and lines 15-22); and running the delivery program, the delivery program executing the set of operating, parameters thereby controlling the infusion pump to deliver the

therapeutic agent according to the delivery schedule defined by the set of

operating parameters (0073, lines 1-8; 0072, lines 1-9);

- downloading the data set to the pump from a computer (Fig. 2, elements 132,

  100);

- storing, a data set in the memory, includes storing two or more data sets in the

  memory, each data set including a set of operating parameters defining a

  delivery schedule (Fig. 3A, element 300; Fig. 6);

- generating a menu, the menu including at least one menu item corresponding to

  one of the unique identifying names; and wherein selecting the unique identifying

  name includes selecting the menu item (Fig. 6, MAIN MENU).

- storing a data set in the memory includes storing a plurality of data sets in

  memory, each data set including a set of operating parameters defining a

  separate delivery schedule (0074, lines 8-17);

- generating a menu includes generating a menu having at least one menu item

  corresponding to a unique identifying name from one data set and at least one

  menu item corresponding to a unique identifying, name from another data set

  (Fig. 6);

- switching execution of the delivery program from the set of operating parameters

  in one data set to the set of operating parameters in another data set (0074, lines

  1-17).

As for claims 19-25, **Estes** discloses,

- an infusion pump comprising: a pump mechanism (Fig. 2, element 100); memory

  storing a data set (Fig. 1, element 106), the data set including a set of operating

  parameters defining a delivery schedule (Fig. 6, Bolus Delivery), at least one of

  the operating parameters being a uniquely identifying name (Fig. 6, BOLUS,

  SUSPEND, BASAL); and a processor arranged to control the pump mechanism

  and in data communication with the memory (Fig. 1, elements 102, 106, 124), the

  processor being programmed to assign the set of operating parameters to the

  delivery program upon selection of the uniquely identifying name and to execute

  the set of operating parameters thereby controlling the pump mechanism to

  deliver the therapeutic agent according to the delivery schedule (Fig. 6, i.e.,

  BOLUS, SUSPEND, BASAL: 0065, lines 1-20, 0074, lines 8-17);

- a data port, the processor being further arranged to control downloading of the

  data set and storage of the data set into tile memory (Fig. 2, elements 132, 130,

  100);

- the memory stores two or more data sets ill the memory, each data set including

  a set of operating parameters defining a delivery schedule (Fig. 3A, element 300;

  Fig. 6);

- the processor is further programmed to generate a menu, the menu including at

  least one menu item corresponding to one of the unique identifying names,

  wherein selecting the menu item is at least one step in beginning execution of the

  delivery program (Fig. 6, MAIN MENU);

- the memory stores two or more data sets, each data set including a set of

  operating parameters defining a separate delivery schedule (0074, lines 8-17);

- the processor is further programmed to generate a menu, the menu including at

  least one menu item corresponding to a unique identifying, name from one data

  set and at least one unique identifying name from another data set (Fig. 6);

- the processor is further programmed to switch execution of the delivery program

  from the set of operating parameters in one data set to the set of operating

  parameters in another data set (0074, lines 1-17).

Response to Arguments

2.   Applicant's arguments filed April 21, 2005 have been fully considered but they

are not persuasive.

Regarding claims 1-11, Applicant contends that **Estes** fails to disclose

"generating a table on the computer, entering operating parameter into at least one cell

and downloading the operating parameters into the pump". Examiner disagrees

because the claims are so broad as to read in **Estes** who discloses *generating a table*

on the computer (Fig. 3A, element 300; Fig. 5, Alarm/Event Marker Table, i.e., the Table

has rows that includes a plurality of cells such as the cell where the time is indicated,

"12:58 AM" and the cell "Bolus Est.") *entering operating parameter into at least one cell*

(Fig. 5, Alarm/Event Marker Table, i.e., the Table has rows that includes a plurality of

cells such as the cell where the time is indicated, "12:58 AM" and the cell "Bolus Est.";

Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived

from carbohydrate consumption events from **the event marker table that have been**

logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in

either 12 or 24 hr format **depending on user's settings**", [0064], lines 13-15, i.e., "At

least **some of these events can be taken as inputs to the bolus estimator 128** in

calculating an insulin dosage") and *downloading the operating parameters into the*

pump (Page 6, [0060], lines 6-8, i.e., "The event markers can be logged into the pump

and stored for later downloading or entered directly into the running software program";

0035, lines 1-7).

Applicant contends that **Estes** teaches downloading from a pump to a PC

computer or a remote communication device, <u>not</u> from a computer to a pump.

Examiner disagrees because Estes clearly teaches bidirectional communication

between the computer and the infusion device or pump (Fig. 2). Estes teaches that the

programming can either be entered directly into the infusion device using the input

device 108 or transferred from the computer 132 ([0035]). Referring to Fig. 5 with

respect to the Event Marker Table **Estes** teaches that "The event markers can be

logged **into** the pump and stored for later downloading".

With respect to claim 12-23, Applicant contends that Estes does not teach that a

user can assign the name of a function. Applicant further contends that Estes does not

disclose that the uniquely identifying name is a part of the data set. Examiner disagrees

because Estes teaches selecting or assigning the name of a function (Fig. 6, i.e.,

SUSPEND). Estes further teaches that the uniquely identifying name, i.e., SUSPEND,

is a part of the data set (Page 8, [0073], i.e., Upon selecting the suspend function, the
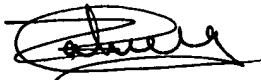
user is presented with a menu to select the period for suspension. Therefore, the data

set corresponds to the period for suspension).

Conclusion

4.   Any inquiry concerning communication or earlier communication from the

examiner should be directed to Zoila Cabrera, whose telephone number is (703) 306-

4768. The examiner can normally be reached on M-F from 8:00 a.m. to 5:30 p.m. EST

(every other Friday).

If attempts to reach the examiner by phone fail, the examiner's supervisor, Leo

Picard, can be reached on (703) 308-0538. Additionally, the fax phones for Art Unit

2125 are (703) 872-9306. Any inquiry of a general nature or relating to the status of this

application should be directed to the group receptionist at (703) 305-9600.

Zoila Cabrera
Patent Examiner
6/10/05